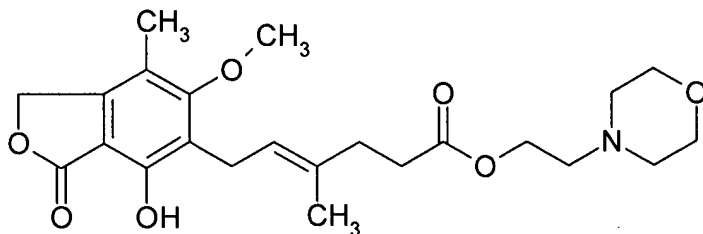


Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (currently amended) Process for the purification of mycophenolate mofetil [~~mycophenolic acid~~ 2-(4-morpholinyl)ethyl ester] of formula I



by removing its by-products, whereby a solution or suspension of mycophenolate mofetil is treated with a primary or secondary amine.

2. (currently amended) Process according to claim 1, ~~characterised in that~~ wherein the by-products contain dimers.

3. (currently amended) Process according to claim 1 ~~or 2, characterised in that~~ wherein the primary or secondary amine has the following formula:



- whereby R₁ is hydrogen or Y, and
- whereby X and Y may be identical or different, and X or Y may each be
 - a) hydrogen, or
 - b) an optionally substituted C₁-C₁₂-alkyl group, which is optionally interrupted by a hetero atom from the series nitrogen, oxygen or sulphur or by an alkylene group, or
 - c) an optionally substituted aryl group, or
 - d) an optionally basic aromatic heterocycle, or
 - e) an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen, or
- whereby X with R₁ forms an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen.

4. (currently amended) Process according to claim 3, ~~characterised in that~~ wherein the substituents are selected from the group consisting of alkyl, carboxyl, alkoxy groups, ~~or~~ hydroxy groups, ~~or~~ and aryl groups which optionally contain alkyl, carboxyl, alkoxy or hydroxy groups, or are amino groups, monoalkyl- or monoaryl-amines, dialkyl- or diaryl-amines, a trialkylammonium or triaryl ammonium group, a cyclic amine or a basic heterocycle.

5. (currently amended) Process according to claim 4, ~~characterised in that~~ wherein the substituents stem from the groups n-butylamine, ethylenediamine, diaminobutane, diaminopentane, diaminohexane, diaminocyclohexane, or dimethylaminopropylamine, for example 3-N,N-dimethylamino-1-propylamine.

6. (currently amended) Process according to ~~one of claims 1 to 5~~, ~~characterised in that~~ wherein the primary or secondary amine is soluble in an organic solvent.

7. (currently amended) Process according to claim 6, ~~characterised in that~~ wherein the organic solvent is selected from the group consisting of includes a ketone, ~~for example acetone or methyl isobutyl ketone, or a C₄-C₄-alcohol, or a nitrile, for example acetonitrile, or~~ and an inert solvent, optionally in the presence of a cosolvent, or mixtures thereof.

8. (currently amended) Process according to claim 7, ~~characterised in that~~ wherein the inert solvent is an acetic acid (C₁-C₄)-alkyl ester or a halogenated hydrocarbon, optionally in the presence of a cosolvent.

9. (currently amended) Process according to claims 7 ~~or 8~~, ~~characterised in that~~ wherein the inert solvent is ethyl acetate, isopropyl acetate or dichloromethane, optionally in the presence of a co-solvent.

10. (currently amended) Process according to ~~one of claims 7 to 9~~, ~~characterised in that~~ wherein the cosolvent is an organic amide.

11. (currently amended) Process for the purification of mycophenolate mofetil, ~~characterised in that it comprises the following reaction steps comprising:~~

- a) activation of mycophenolic acid by forming a reactive derivative in an inert solvent,
- b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,
- c) treating it with a primary or secondary amine, and
- d) isolating the mycophenolate mofetil.

12. (original) Process for the purification of mycophenolate mofetil, which contains by-products, characterised in that it comprises the following reaction steps:

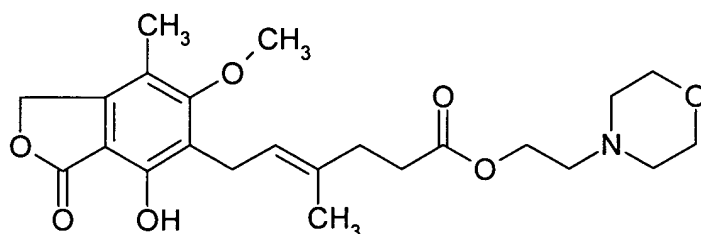
- a) preparing a solution or suspension of mycophenolate mofetil as a free base in an inert solvent,
- b) treating it with a primary or secondary amine, and
- c) isolating the mycophenolate mofetil.

13. (currently amended) Process according to claim 12, ~~characterised in that~~ wherein the by-products contain dimers.

14. (original) Mycophenolate mofetil as the free base with a maximum content of dimers of 0.15% (area percent HPLC).

15. (original) Mycophenolate mofetil as the free base with a content of dimers of 0.15 to 0.03% (area percent HPLC).

16. (currently amended) Process for the production of mycophenolate mofetil [~~mycophenolic acid 2-(4-morpholinyl)ethyl ester~~] of formula



~~whereby~~ wherein a reactive derivative of mycophenolic acid is produced in an inert solvent and is reacted with 4-(2-hydroxyethyl)morpholine, and the resulting mycophenolate mofetil is isolated from the reaction mixture, ~~characterised in that~~ wherein

- I) 4-(2-hydroxyethyl)morpholine is added under controlled conditions to the solution of the reactive derivative of mycophenolic acid, whereby the reaction takes place under acidic reaction conditions, and
- II) isolation of mycophenolate mofetil is effected by forming an acid addition salt and subsequently releasing the free base.

17. (currently amended) Process according to claim 16, ~~characterised in that it contains the following process steps~~ which additionally comprises:

- a) activation of mycophenolic acid by forming a reactive derivative

- b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,
- c) isolating mycophenolate mofetil through the formation of an acid addition salt, and
- d) releasing the free base of mycophenolate mofetil from the acid addition salt.

18. (currently amended) Process according to ~~one of claims 11, 16 or 17, characterised in that~~ wherein the reactive derivative of mycophenolic acid is an acid halide.

19. (currently amended) Process according to claim 18, ~~characterised in that~~ wherein the acid halide is an acid chloride.

20. (currently amended) Process according to ~~one of claims 16 to 19, characterised in that~~ wherein the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

21. (currently amended) Process according to ~~one of claims 16 to 20~~ comprising the following process steps:

- a) activation of mycophenolic acid by forming a reactive derivative,
- b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,
- c) treating the reaction mixture with a primary or secondary amine,
- d) isolating mycophenolate mofetil through the formation of an acid addition salt, for example the oxalate, and
- e) releasing the free base of mycophenolate mofetil from the acid addition salt.

22. (currently amended) Process for the purification of mycophenolate mofetil, ~~characterised in that it comprises the following reaction steps comprising:~~

- a) preparing a solution or suspension of mycophenolate mofetil as an acid addition salt in an inert solvent,
- b) releasing the free base,
- c) treating it with a primary or secondary amine, and
- d) isolating the mycophenolate mofetil.

23. (currently amended) Process according to claim 22, ~~characterised in that~~ wherein the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

24. (original) Mycophenolate mofetil as the oxalate with a maximum content of dimers of 0.1% (area percent HPLC).

25. (original) Mycophenolate mofetil as the oxalate with a content of dimers of 0.1 to 0.03% (area percent HPLC).